DECLARATION OF CONFORMITY

We, RIVERSTONE RESOURCES SDN. BHD.
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declare under our sole responsibility that the medical device described hereafter:

NITRILE EXAMINATION GLOVES (Powder Free)

under Classification (MDD, Annex IX): **Class I, Rule 5**
has meet the provisions of the MDD 93/42/EEC*(as amended by Directive 2007/47/EC)* and other relevant harmonized standards as follows:-

EN ISO 13485	**Medical Devices- Quality management systems - Requirements for regulatory purposes**
ISO 14971	**Medical devices- Application of risk management to medical devices**
ISO 10993-5	**Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.**
ISO 10993-10	**Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity**
ISO 15223-1	**Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements**
EN 980	**Symbols for use in labelling of medical devices**
EN 455-1	**Requirements and Testing for Freedom from Holes**
EN 455-2	**Requirements and Testing for Physical Properties**
EN 455-3	**Medical Gloves for Single Use – Part 3 : Requirements and Testing for Biological Evaluation**
EN 455-4	**Requirements and testing for shelf life determination.**
ASTM D3578	**Standard Specification for Rubber Examination Gloves**
ASTM D5151	**Standard Test Method for Detection of Holes in Medical Gloves**
ASTM D5712	**Standard Test Method for Analysis of Protein in Natural Rubber and its Products using the Modified Lowry Method**
ASTM D6319	**Standard Specification for Nitrile Examination Gloves For Medical Application**
ASTM D412	**Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers – Tension**

following the provisions in conformity assessment procedure listed in Annex VII of Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC).This declaration is supported by the Quality System certification based on the harmonized standard **ISO 13485:2003**, Quality System Certificate with reference number **MY10/00550** issued for the first time on 25th June 2010 and delivered by Notified Body **SGS United Kingdom Ltd Systems & Services Certification** located at Rossmore Business Park, Ellesmere Port, Cheshire, CH65, 3EN, UK.

The European Authorised Representative, Obelis S.A. is located at Boulevard Général Wahis 53, 1030 Brussels, Belgium.

All supporting documentations are retained at the premises of the manufacturer.

Riverstone Resources Sdn. Bhd.

Managing Director (MD)	Plant Manager	QA Manager
Date: 2nd April 2015	Date: 2nd April 2015	Date: 2nd April 2015